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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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1041 ROUTE 202-206				
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BRIDGEWATER, NJ 08807				
EXAMINER				
KOSSON, ROSANNE				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
03/19/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/076,631

Applicant(s)

HABERMANN, PAUL

Examiner

Rosanne Kosson

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.6-12 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.6-12 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicant's amendment filed on January 22, 2009 has been received and entered. Claim 1 has been amended. Claims 13-37 have been canceled. Claim 38 has been added. Accordingly, claims 1, 6-12 and 38 are examined herewith to the extent that the claims read on the elected invention. As discussed in Applicant's response to a restriction requirement on September 29, 2005, regarding the variables recited in the claims, P is the ADH2 promoter, S is the yeast alpha mating factor leader sequence, B is a chemical bond, Z1 is a codon for K, Z2 is a codon for R and T is a 3' interleukin-2 sequence.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In view of Applicant's amendments to the claims, the objection to claims 27-37 as being duplicates of claims 1 and 6-12 is withdrawn.

Claim 1 is objected to because of the following informalities. The claim is drawn to a polynucleotide comprising a number of different components, but some of the components are described as polypeptides and some of the components are described as polypeptides. The two seem to be used interchangeably. See lines 2-7, 13 and 17. Lines 3-7 recite a peptide encoded by a transport peptide and a protein encoded by protein(Y). Line 13 recites a transport protein comprising a nucleic acid sequence. Line 17 recites that protein Y comprises a nucleic acid sequence. Lines 3-7 may be deleted. Alternatively, "peptide encoded by" in line 3, "protein encoded by said" in line 4, "peptide encoded by" in line 6 and "protein encoded by said" in line 7 may be deleted. Line 2 should be amended to recite a nucleic acid encoding a transport

peptide and a nucleic acid encoding protein(Y). Line 13 should be amended to recite that the transport peptide is a hirudin or lepirudin. Line 17 should be amended to recite that protein(Y) is mini-proinsulin or insulin. Appropriate correction is required.

Also, claims 1 and 38 recite a nucleic acid sequence. These claims should be amended to recite a nucleic acid. Sequences are analogous to chemical formulas and are therefore not patentable subject matter. Also, claim language consistent with that of claims 6-8, which refer to the nucleic acid of claim 1 is needed. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

In view of Applicant's amendments to the claims, the written description and enablement rejections in the previous Office action of claims 1 and 6-12 are withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicant's amendments to the claims, the rejections in the previous Office action of claims 1 and 6-12 are withdrawn.

Double Patenting- Obviousness-type

As discussed in the previous Office actions, claims 1 and 6-12, and now new claim 38 as well (which corresponds to patented claim 4), are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4-10 of US Patent No. 7,202,059 (identical to claims 1, 2, 4, 5 and 9-13 of copending Application No. 10/076,634). This rejection was discussed in the previous Office action (the broad language of the patented claims encompasses the instant claims).

Applicant asserts that only claim 1 was rejected and that the rejection is provisional. In

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reply, all of the pending claims were rejected, and the rejection is actual, in that it is a real rejection, not a potential rejection. This rejection is still outstanding and must be addressed. Appropriate correction is required.

Similarly, claims 1 and 6-12, and now new claim 38 as well (which corresponds to copending claim 33), are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-13 and 31-35 of copending Application No. 10/076,632 (published as US 2003/0176673 A1). This rejection was discussed in the previous Office action (the broad comprising language of the copending claims encompasses the instant claims).

As discussed above, Applicant asserts that only claim 1 was rejected and that the rejection is provisional. In reply, all of the pending claims were rejected, and the rejection is actual. Provisional does not mean potential or future. This rejection is still outstanding and must be addressed. Appropriate correction is required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1652
rk/2009-03-02

/Delia M. Ramirez/
Primary Examiner, Art Unit 1652